

June 22, 2006

Congressman Henry Waxman
Ranking Minority Member
Committee on Government Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Congressman Waxman:

At your request, I have reviewed the case files that were provided by the Food and Drug Administration to the Committee on Government Reform. Based on my 29 years of experience working at FDA, including 17 years in enforcement, I am very concerned about current enforcement procedures at FDA as depicted in these documents.

During my career at FDA, I worked in many positions. I spent the first eight years in the field, at the Dallas and Philadelphia District Offices. In 1971, I transferred to FDA headquarters, where I worked on both regulatory and enforcement matters. I served as Director of the Division of Compliance in the Bureau of Biologics for eight years, then in positions of enforcement in the Center for Drug Evaluation and Research for the next nine years, until I retired in 1992.

Based on my experience and expertise in this field, I have serious concerns about how FDA is currently fulfilling its enforcement responsibilities. These documents involve many cases where FDA headquarters overruled the clear and thorough recommendations of field offices to take enforcement action against a firm. In most of these instances, the explanation given by FDA headquarters for the decision was inadequate or unreasonable. Taken together, the documents indicate that staff at FDA headquarters regularly minimize the concerns of field staff, despite the well-supported arguments that field staff present in favor of enforcement action. Overall, these documents tend to represent a culture of disapproval or a lack of full dedication to the protection of the public health.

Officials at FDA often relied on several inappropriate or false arguments to support their denials of field office recommendations. For example, in several cases, FDA suggested that "in the absence of adverse events, product failures and recalls, or health hazard," enforcement action was not necessary. This argument is improper and has no founding in law or regulation. Nothing in the legislative history or case law supports that a charge of adulteration is contingent on a showing of actual harm to a consumer or actual failure of a product. Instead, the law


provides that any failure to conform to manufacturing standards will render a product adulterated.

I also am disturbed by the disparity in many cases between the findings of field inspectors and the conclusions reached by FDA headquarters staff. Officials at FDA headquarters frequently minimized the inspectors' observations, choosing to discount findings that were based on thorough, in-person investigations. I find this alarming, given that inspectors have the most direct and complete knowledge of the operations of a subject firm. In my opinion, it is inappropriate and dangerous for FDA headquarters to discount the findings of field inspectors in this way.

In summary, these documents suggest that FDA is not fully carrying out its mission of protecting the public health. By minimizing and overruling the recommendations of field staff on a regular basis, the agency is undermining its goal of vigorous enforcement as an essential tool of ensuring compliance with the law.

I hope that my review of these documents is of some assistance to your investigation of these important matters.

Sincerely,


Sammie R. Young